(c) whether it is a fact that the medicine has been withdrawn in many countries and its marketing banned;

(d) whether Government propose to take similar action in this regard; and

(e) if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (c) Nimesulide, non-steroidal anti-inflammatory drug (NSAID), is reported to be used in about 50 countries including India and is indicated for acute pain/inflammation and fever.

In March 2002, the National Agency for medicines in Finland decided to suspend the distribution of Nimesulide, while keeping its market authorisation in force as undesirable effects on liver were reported. Review by Finland agency is underway. The use of Nimesulide was also temporarily suspended in Spain and Turkey. The EMEA (European Medicinal Evaluation Agency) has started the review of Nimesulide.

(d) and (e) As a part of ongoing review an exercise is being undertaken by expert committee constituted by Drugs Technical Advisory Board to deliberate on the issues concerning the safety of Nimesulide. As regard to the use of Nimesulide in children the expert committee was of the view that immediate opinion of at least 20 well known paediatricians across the country may be obtained alongwith the information available from ADR centres. After gathering all relevant information the expert committee will examine the matter in detail and give its recommendations.

Regulatory standards on medical devices

35. SHRI RAMA MUNI REDDY SIRIGIREDDY:
SHRI K. RAMA MOHANA RAO:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there is any plan of his Ministry to bring in regulatory standards on the medical devices manufactured by various manufacturers in the country;

(b) whether the proposed standards are also applicable to the items imported into the country; and

(c) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (c) Section 3 (b), (iv) of Drugs and Cosmetics Act provides for regulating Medical Devices as notified by the Government from time to time. Presently, devices like (i) Disposable Hypodermic Syringes, (ii) Disposable Hypodermic Needles, (iii) Disposable Perfusion Sets, (iv) Invitro Diagnostic Kits for HIV, HbSAg & HCV have been notified and their Standards have been prescribed which are applied even to these items imported into the country.

Mental disorders

36. SHRI KRIPAL PARMAR:
SHRI B.J. PANDA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government's attention has been drawn to the news-item captioned, "At AIIMS, mental health takes a backseat", which appeared in the Indian Express, dated 22nd August, 2002;

(b) if so, the reasons for this bad state of affairs;

(c) whether Government are aware that as per WHO report of April, 2001, mental disorders are on the rise and it has declared mental disorders as world emergency; and

(d) if so, whether Government propose to upgrade, modernize and revamp the Department of Psychiatry?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) The Indian Express, New Delhi edition of 22nd August, 2002 (late City) has been perused. No such news items could be located.

(b) In All India Institute of Medical Sciences, New Delhi, the Department of Psychiatry is performing Walk-in-Clinic where patients referred from other departments or registered as new cases are seen on